

DEC 14 1999



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

M.C. Meinert, Esq.
Genetics Institute, Inc.
Legal Affairs
87 CambridgePark Drive
Cambridge, MA 02140

Re: Patent Term Extension
Application for
U.S. Patent No. 5,171,569

Dear Ms. Meinert:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,171,569 for a period of 423 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: rFIX
FDA Docket No. 97E-0168

kt

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

PATENT NO. : 5,171,569
ISSUED : December 15, 1992
INVENTORS : Donald S. Anson, et al.
PATENT OWNER : British Technology Group Limited
PRODUCT : BeneFIX™ (coagulation factor IX (Recombinant))

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

423 days

from December 15, 2009, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the Patent and Trademark Office to be affixed this 10th day of December 1999.

A handwritten signature in dark ink, appearing to read "Q. Todd Dickinson".

Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks